June 2, 2015 CDC Ebola Response Update

[Announcer] This program is presented by the Centers for Disease Control and Prevention.

[Stephanie Nguyen] You may know that CDC and others have been working to develop vaccines to protect against Ebola. Right now, *no* vaccines are proven to protect people from getting Ebola. However, we believe it *is* possible to have a vaccine to help protect people during this outbreak or in future ones. Joining me today to talk about the latest vaccine trial sponsored by the CDC is Dr. Jane Seward, Deputy Director of the CDC's Division of Viral Diseases. Dr. Seward was in Sierra Leone to lead the CDC's Ebola vaccine trial when it started in early April. Dr. Seward, thank you so much for being here today.

[Dr. Seward] Thanks for having me.

[Stephanie Nguyen] Dr. Seward, tell us about the vaccine trial known as STRIVE.

[Dr. Seward] In April, CDC launched the vaccine trial in partnership with the Sierra Leone College of Medicine and Allied Health Sciences, and the Sierra Leone Ministry of Health and Sanitation. STRIVE stands for "Sierra Leone Trial to Introduce a Vaccine against Ebola." This vaccine trial is a combined Phase 2 and 3 clinical trial designed to look at three things:

- If and how well one of the candidate Ebola vaccines in development, called the rVSV-ZEBOV vaccine, helps protect people from getting Ebola,
- If that vaccine is as safe as early small studies suggest, and
- The immune response, or how well people develop antibodies, to the vaccine.

The study will enroll at least 6,000 health and other frontline workers in Sierra Leone and it is taking place in five of the districts that have been most heavily affected by the Ebola outbreak.

[Stephanie Nguyen] How does the study work?

[Dr. Seward] Once enrolled, STRIVE participants are randomly assigned to one of two timeframes for vaccination: immediately or about six months after enrollment. Every participant will receive the vaccine and be monitored for six months after vaccination. This allows researchers to evaluate if, and how well, the vaccine works by comparing rates of Ebola in those vaccinated immediately to those who have not yet been vaccinated.

[Stephanie Nguyen] Dr. Seward, what do we know about the vaccine used in STRIVE?

[Dr. Seward] This vaccine is also being used in trials in Liberia and Guinea. It was developed by the Public Health Agency of Canada and licensed to NewLink Genetics Corporation and Merck. This vaccine is designed to protect against *Zaire ebolavirus*, the strain causing the current outbreak in West Africa.

Researchers don't yet know if this vaccine will help protect people from getting Ebola, by how much, or how long protection will last. They *do* know that this vaccine *cannot cause* Ebola because it only contains a single Ebola virus gene and only the *whole* virus can cause disease.

[Stephanie Nguyen] What is known about the safety of the vaccine? Are there any side effects?

[Dr. Seward] This particular vaccine was studied in more than 500 people in other countries without any vaccine-related serious adverse events or deaths. Including STRIVE and other trials, more than 3,000 people have now received this vaccine. People who get the vaccine may experience mild side effects, including a sore arm, fatigue, fever, headache, or muscle ache. These reactions occur in about one out of two people who get the vaccine, and about one out of eight people may feel nauseous. These side effects usually happen within the first 24 hours after vaccination and typically get better in one to two days. Some people who get this vaccine get mildly painful swelling of the joints, a mild skin rash, blisters, or mouth ulcers in the second week after vaccination, but these side effects also usually get better in about one or two weeks or less. Like with other candidate vaccine studies, when larger numbers of people get vaccinated, additional side effects may be seen.

[Stephanie Nguyen] So we know the vaccine can't *cause* Ebola, but can those who receive the vaccine still *get* Ebola?

[Dr. Seward] That's a great question and a very important point. Although the vaccine cannot *cause* Ebola, a person who is vaccinated *can* still *get* Ebola for several reasons:

- If they were infected before they got their vaccine,
- If they are exposed to Ebola before the vaccine has a chance to build up protection in the body, or
- If they're exposed *after* getting vaccinated and the vaccine doesn't fully protect them from Ebola.

Remember, we don't know yet if, or how well, the vaccine works. That's why those who get the vaccine still need to take other actions to protect themselves from getting Ebola. They should practice good hand hygiene, wear recommended personal protective equipment, be careful with needles when taking care of patients, and not treat patients outside of health facilities.

[Stephanie Nguyen] Dr. Seward, it's been about a month and a half since the vaccine trial began in Sierra Leone. Give us an update. How are things going?

[Dr. Seward] The trial is going very well and six of the seven sites are now enrolling participants and vaccinating those randomized to receive immediate vaccine. As of May 31, over 5,250 participants have been enrolled in STRIVE and over 2,450 have been vaccinated.

[Stephanie Nguyen] We've been talking to Dr. Jane Seward about the Sierra Leone vaccine trial. To learn more, visit cdc.gov/Ebola.

[Announcer] For the most accurate health information, visit www.cdc.gov or call 1-800-CDC-INFO.